Eye Care Menu

Service Manual

French Version

German Version

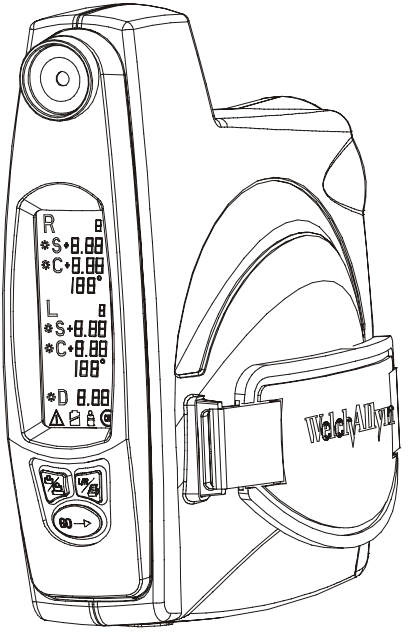
Italian Version

Spanish Version

Welch Allyn®

SureSight™

Autorefractor



Welch Allyn®

4341 State Street Road
Skaneateles Falls, NY 13153-0220

140400 Rev. B

Welch Allyn®
SureSight™
Autorefractor

Table of Contents

Warnings & Symbols 1
Mises en garde et symboles 4
Technical Specifications 8
Function and Intended Application 10
SureSight Display, Controls, and Features 11
First Time Set-Up 13
- Stand 13
- Battery 13
- Plus or Minus Cylinder Convention 14
- Diopter Power Resolution 14

Controls 15
Operating Instructions 16
- Important Operating Tips 18
- Helpful hints for testing pre-schoolers 18
- Results 19
- Adult/Child Calibration 20
- Adult/Child Mode Tips 20

Replacement and Recycling of Battery 20
- Replacing the Battery 20
- Charging 21
- Recycling Lithium Ion Battery 21

Screening Mode and Software Updates 22
Screening Mode 22
Updating SureSight Software 22
Hand Strap Replacement 23
Cleaning and Sterilization of the SureSight 23
Service, Calibration, and Warranty Information 24
Warranty 24
Service and Warranty 25
SureSight Rechargeable Battery 25
Calibration and Maintenance 25

Warnings & Symbols

ATTENTION: Refer to the operating instructions. This symbol (⚠) is intended to advise the user of the presence of important operating or maintenance instructions in the documents accompanying the instrument.

Service or Repair to be performed by qualified, authorized personnel only. There are no user serviceable parts inside the instrument. Opening this device can expose the user to harmful invisible laser radiation.

Use only with Welch Allyn 710 series chargers.

Replacement parts and accessories - Use only approved replacement parts and accessories specified in this manual. Refer to the maintenance section of this manual for more information.

Do not sterilize the instrument or any of its components.

Use only with IEC 60601-1 approved printers, or keep printer out of patient vicinity.

Disassembly of instrument beyond the extent described in this manual will void the warranty. Refer all servicing to Welch Allyn or a Welch Allyn authorized service representative listed in the Servicing, Calibration and Warranty Information section. Opening this device can expose the user to harmful invisible laser radiation. Only the battery cover is to be opened by the user.

Battery replacement: Replace with Welch Allyn model # 72420 Lithium Ion battery only.

Do not attempt to disassemble or modify the battery pack. There are no user serviceable parts inside pack.

Do not attempt to directly solder to the battery pack.

Do not attempt to connect the positive and negative battery terminals to each other, nor to any other device.

"Caution" - use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous radiation exposure.

Do not operate, charge, leave or discard battery pack in any environment where it may exceed 0°C to 40°C.

Do not immerse the battery pack in water.

Do not attempt to open or pierce the battery pack.

Do not strike or throw the battery pack.

Do not use a battery pack which appears to be deformed, leaking, corroded, or is otherwise irregular.

If electrolyte leaking from battery contacts your skin or eyes, rinse with running water and immediately seek medical attention.

IPXØ: Not protected against the ingress of water.

Not for use in the presence of flammable anesthetics.

Type BF Equipment.

Double Insulated.

ETL listed: UL2601-1, CSA C22.2 No. 601.1, IEC 60601-1, AS 3200.1. IEC 60601-1-2

Australia EMC Framework Compliance

The CE mark on this device indicates that it has been tested and conforms to the provisions noted within the 93/42/EEC Medical Device Directive.

Mises en garde et symboles

ATTENTION : Consulter le mode d'emploi. Ce symbole (⚠) signale à l'utilisateur la présence de renseignements importants relatifs au fonctionnement ou à l'entretien de l'instrument dans les documents qui l'accompagnent.

L'entretien ou la réparation ne doivent être effectués que par un personnel compétent habilité. Cet instrument ne contient pas de pièces réparables par l'utilisateur. L'ouverture de ce dispositif risque d'exposer l'utilisateur à un rayonnement laser invisible nocif.

Utiliser uniquement avec des chargeurs Welch Allyn série 710.

Pièces et accessoires de rechange – Utiliser uniquement les pièces et accessoires de rechange autorisés spécifiés dans ce manuel. Consulter la section Entretien de ce manuel pour des informations supplémentaires.

Ne pas stériliser l'instrument ni aucun de ses composants.

Utiliser uniquement avec une imprimante conforme à la norme CEI 60601-1, ou utiliser l'imprimante à distance du patient.

Un démontage de l'instrument au-delà des recommandations de ce manuel annule la garantie. Confier toutes réparations à Welch Allyn ou à un représentant agréé par Welch Allyn listé dans la section Informations sur les réparations, l'étalonnage et la garantie. L'ouverture de ce dispositif risque d'exposer l'utilisateur à un rayonnement laser invisible nocif. Seul le couvercle de la batterie peut être ouvert par l'utilisateur.

Remplacement de la batterie : Remplacer uniquement par une batterie au lithium Welch Allyn modèle n^{o} 72420.

Ne pas essayer de démonter ou de modifier le bloc-batterie. Il ne contient pas de pièces réparables par l'utilisateur.

Ne pas essayer de souder directement sur le bloc-batterie.

Ne pas essayer de relier les bornes positive et négative l'une à l'autre, ou à d'autres dispositifs.

Attention : Des procédures de contrôle, de réglage ou de performance autres que celles qui sont spécifiées dans cette notice peuvent entraîner une exposition dangereuse au rayonnement.

Ne pas activer, charger, laisser ou jeter le bloc-batterie à un endroit où la température ambiante est inférieure à 0° C ou supérieure à 40° C.

Ne pas immerger le bloc-batterie dans l'eau.

Ne pas essayer d'ouvrir ou de percer le bloc-batterie.

Ne pas frapper ni lancer le bloc-batterie.

Ne pas utiliser un bloc-batterie qui semble fuir ou être déformé, corrodé ou anormal.

En cas de contact cutané ou oculaire avec une fuite d'électrolytes de la batterie, rincer à l'eau courante et consulter immédiatement un médecin.

IPXØ : Non protégé contre l'infiltration d'eau.

Ne pas utiliser en présence d'anesthésiques inflammables.

Equipement de type BF.

Double isolation.

Homologations ETL : UL 2601-1, CSA C22.2, N^{O} 601.1 et IEC 60601-1,
AS3200.1, IEC 60601-1-2

Obedece la norma australiana EMC Framework

La marque CE appliquée sur ce dispositif indique qu'il a été testé et déclaré conforme aux dispositions de la directive 93/42 de la CEE sur les appareils médicaux.

Authorized European Representative Address:
European Regulatory Manager
Welch Allyn, Ltd.
Kells Road, Navan
County Meath, Republic of Ireland
Telephone: 353-46-28122
Fax: 353-46-28536

Note: This product complies with current required standards for electromagnetic interference and should not present problems to other equipment or be affected by other devices. As a precaution, avoid using this device in close proximity to other equipment.

Note: This product contains no hazardous materials. Its disposal will not contaminate or harm the environment, or present any risk to individuals disposing of the product. As a precaution, it is recommended you contact your local disposal and/or recycling authority for information regarding the disposal of the equipment.

Technical Specifications

Technology:	Welch Allyn proprietary autorefractor hardware/ algorithm
Working distance:	14 inches (35 cm.)
Distance detection:	Automatic, with audible and visual cues
Eyepiece:	Illuminated target for easy aiming
Data acquisition time:	2.4s/eye
Data acquisition:	Measures and averages 5 to 8 readings/eye
Reliability measure:	Indicates number of and variation among measurements for the given eye
Diopter display:	1/8 or 1/4 diopter increments
Axis:	1(increments
Stand:	Compact charger and SureSight storage
Weight:	Approximately 2.0 lbs. (0.9 Kg.)
Dimensions:	6.5" x 7.75" x 2"
Class II equipment:	Continuous operation.
Transport/Storage:	-20°C~49°C, 10%(100% R.H. Max, 500hPa - 1060hPa Altitude
Operating:	10°C~30°C, 30%(75% R.H. Max, 500hPa - 1060hPa Altitude
Measurement Range:	Sphere: +6.0 to -5.0 Diopters
	Cylinder: (3 Diopters
Battery voltage:	7.2v nominal (Lithium Ion)
Battery life:	More than 3 hours of continuous usage

Low-Battery warning:	Indicates 10 - 15 minutes usage remains
Interfaces:	Remote infrared link to thermal printer. RS-232 interface for IBM compatible PC for future software upgrades/data transfer to electronic medical records.
Laser safety:	Class 1 Laser Product per CDRH 21CFR 1040.10 and 1040.11, IEC 825-1 (1996) pending and EN60825-1 (1996) pending
Patents:	US 6,007,204 and Des. 413,979 International Patents Pending
Office illumination:	Not for use in direct sunlight. Indoor operation only.
Materials:	This product is latex free.
Electromagnetic Compatibility:	FCC Part 15, Class A (USA) This device complies with CFR 47 Part 15, Class A of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference and (2) This device must accept any interference received including interference that may cause undesired operation.

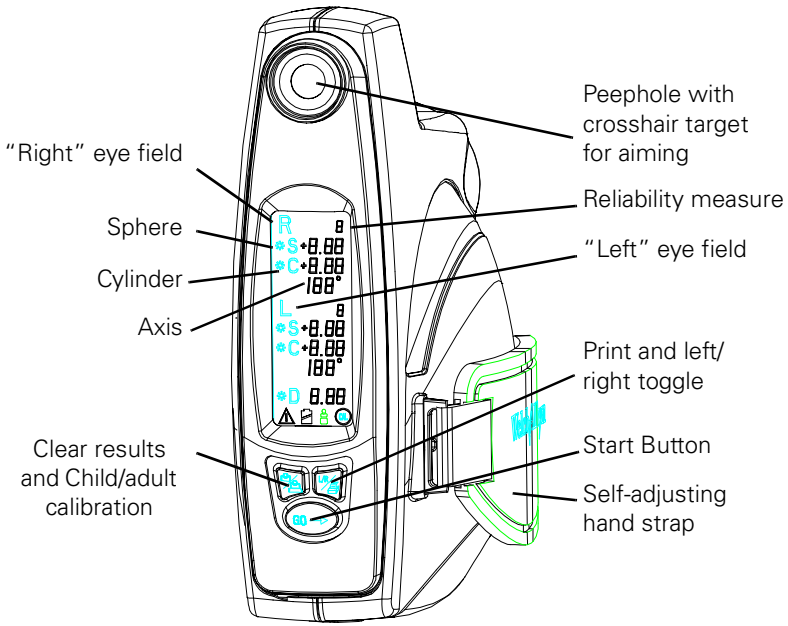
Function and Intended Application

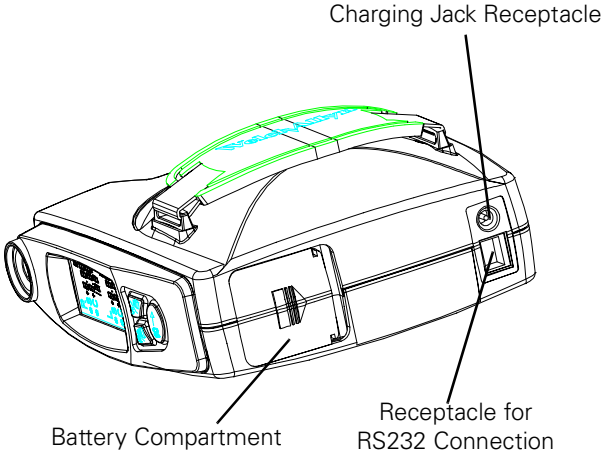
Thank you for purchasing the Welch Allyn SureSight™ Autorefractor. Please read and follow the instructions found in this manual before using your new SureSight to ensure accurate and reliable service.

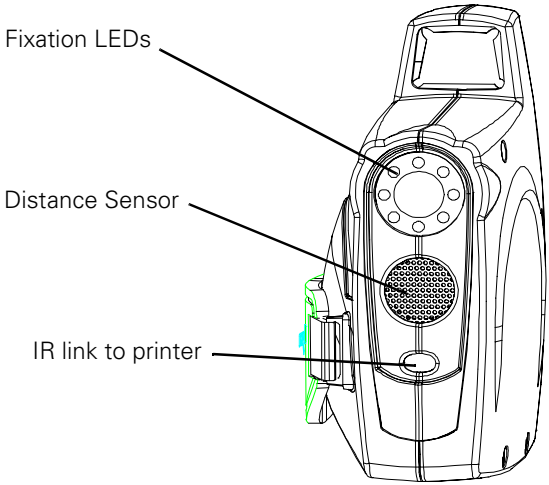
SureSight is the child-friendly, portable autorefractor that lets you test patients - including young children and adults - anytime, anywhere. Carry it from room to room, to your waiting area, even off-site.

SureSight solves many of the problems you face when performing exams. You can perform objective refraction from a non-threatening 14 inches (35 cm) away - even through glasses and contact lenses. The unit's flashing lights and sounds engage the patient throughout the exam. There's no intimidating equipment. No cycloplegic drops to contend with. Just fast, easy refractions. That's why SureSight makes testing even your toughest patients quick and painless - for both you and your patients.

SureSight Display, Controls, and Features




Charging Jack Receptacle
Battery Compartment
Receptacle for
RS232 Connection


Fixation LEDs
Distance Sensor
IR link to printer

First Time Set-Up

Stand

- Insert right angle connector into stand
- Optional: Two strips of hook and loop fasteners are provided on the stand. Attach mating strips to countertop or "home" location of the stand. For best results, clean surface and allow to dry before adhering. Hook and loop fasteners keep stand firmly in place for use, while allowing it to be removed as needed.

Battery

- Insert battery:

1) Open the battery cover located on the underside of the unit by sliding it in the direction indicated by the arrow and lifting out.
2) Insert the new battery into the compartment in the direction of the arrow on the battery itself, so that the terminal end enters the compartment first. If necessary, rotate the lever obstructing the compartment in a clockwise direction until the compartment is unobstructed. NOTE: Insert the battery only as directed. Failure to do so will prevent the instrument from functioning.
3) While pushing in on the battery, rotate the lever in a counter-clockwise direction until it covers the battery.
4) Replace the cover by lightly pushing in on the raised end until it is level and sliding the cover in the opposite direction of the arrow until it locks into place.

Plus or Minus Cylinder Convention

Your SureSight was set at the factory to the Minus Cylinder Convention. If you wish to change your unit to the plus convention:

1) Open the battery cover located on the underside of the unit by sliding it in the direction indicated by the arrow and lift up.
2) Rotate the lever holding the battery in and lift the battery from its compartment.
3) View the DIP switches inside the battery compartment located on the button side of the unit.
4) Using tweezers or another appropriate tool, pull the first switch (located on the side of the unit with the handstrap) up towards the bottom of the SureSight.

Diopter Power Resolution

Your SureSight was set at the factory to display power in 1/4 diopter increments. If you wish to change to 1/8 diopter increments:

1) Open the battery cover located on the underside of the unit by sliding it in the direction indicated by the arrow and lift up.
2) Rotate the lever holding the battery in and lift the battery from its compartment.
3) View the DIP switches inside the battery compartment located on the button side of the unit.
4) Using tweezers or another appropriate tool, pull the third switch (third from side of SureSight with the handstrap) up towards the bottom of the SureSight.

Controls

The buttons on the back of the instrument function as follows:

Child/Adult Calibration

- Clears readings
- Changes child/adult Calibration by holding it down

Left/Right Toggle & Print

- Selects single eye to re-test or switches back to regular test.
- Prints results (hold button down while aiming patient side of SureSight at printer until you hear "tah-dah")

"GO" Button

- **Unit on**: starts test
- **Unit off**: recalls old readings

The instrument will turn off when unused for one minute. Any button pressed on the SureSight will bring up results.

Operating Instructions

- Push any button to turn on the unit.
- Position the patient so that eye levels can be adjusted for unit use.
- Press the child/adult button until you hear a beep to choose the appropriate calibration. (Child/Adult Calibration cut over age is 8 - see Adult/Child Calibration Section, Page 20 for more information).
- Explain the test procedure to the patient:

  "Now I will check your eyes. (Or "Now I'm going to take movies of you.")
  "I want you to look for the red light in the middle of the blinking green lights."
- Position yourself at eye-level and square with the face of the patient.
- Push the "GO" button on the unit and check that the patient is fixated correctly during the test.
- Position the unit at the correct distance from the patient:
  - When too far away, you will hear slow, low-pitched beeps.••••••
  - Slowly move closer. When the unit is at the correct distance (~14"), you will hear a steady, low tone.————
  - When the unit is too close, you will hear quick, high-pitched beeps ·····
  - The cross hairs will flash in synch with the tones.
- When you are at the correct distance, look through the peephole and align the cross hairs on the pupil of the patient's right eye. While the unit is acquiring data, you will hear a very high-pitched chirping sound with a steady low tone. °°°°°
- When the test of the right eye is complete, you will hear the "tah-dah" sound.
- **Rotate** the unit to the left eye and align the cross hair over the left eye's pupil and repeat. (Testing resumes 1 second after the first eye is complete, so you do not need to press any buttons.)
- At the end of the test, you will hear the "tah-dah" sound again.
- If the unit has not gathered enough good readings from either eye, you will hear 5 tones to signify that the testing has stopped. - - - - - You must re-test that eye.

- If you are at the correct distance and not acquiring data:
    - ensure you are level and square with the patient,
    - tell the patient to look into the red light,
    - slowly move the cross-hairs around the eye, and
    - make sure the patient's eyelids are not occluding the pupil
    - aim higher when over-refracting through glasses
- To stop a test at any time, hold any button until 5 tones sound.
- When the unit is off, any button wakes the unit and displays the previous results.
- To Print: Press the print button until beep sounds. Keep unit aimed at printer during beep.
- Do not send 2nd printout to printer before 1st printout has completed printing

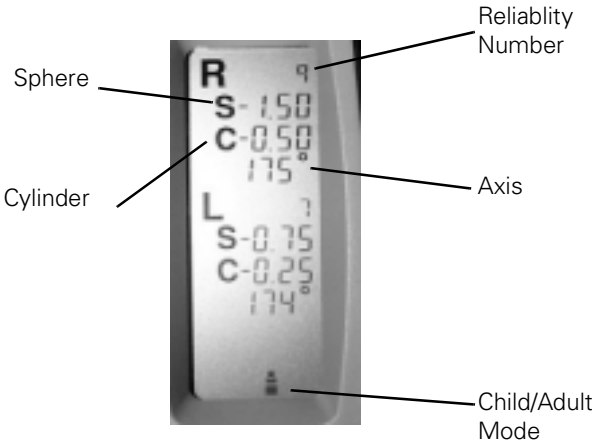
Important Operating Tips

To insure accurate results and quick tests:

- **Ambient Lighting:**
  - Don't perform by uncovered windows
  - Dimmed light can help for adults w/small pupils
    - Too dim can make it harder to find the pupil for those with dark eyes.
- **Entry Angle**
  - Position unit straight and level with patient
  - Rotate unit to test left eye
- **Fixation: "Look at the red light"**
  - Remind patient and monitor fixation
- **Correct Distance/Not Taking Readings?**
  - Are you square and level?
  - Scan around the pupil
  - Ask patient if they see the red light
  - When over-refracting through glasses, aim higher

Helpful hints for testing pre-schoolers

- **Helpful phrases that will grab the child's attention.**
  - "Look into the video camera while I take a movie of you."
  - "Look in the green circle at the red dot inside and you will hear a little birdie chirp."
  - "Look at the red dot inside the flashing green lights and tell me when it changes color."
- **Helpful tips to keeping a child still while administering the test**
  - Have child sit in his/her parent's lap
  - Have child lie down



Results

Reliability Number indicates the number of good readings obtained and their consistency, based on a 1 to 9 scale. The higher the number, the better.

- **≥**6 is typically acceptable*
- 5 is marginal / repeat the test if possible
- **≤**4 is poor / repetition of the test is necessary

*If the patient did not appear to fixate on the unit during data acquisition, repeat the test, even if reliability numbers are **≥**6.

- **S** is the **sphere** in diopters.
- **C** is the **cylinder** power in diopters.

A +9.99 or -9.99 indicates a reading outside the unit's measurement range.

- The SW X.XXe after the date on the printout is the software revision level in the SureSight unit.

Adult/Child Calibration

The adult/child calibration makes three basic changes to the way the unit operates.

- Corrects distance target to match the "size" of the face being tested.
- Selects the proper default accommodation setting.
- Activates the screening referral indicators (in screening mode only).

Adult/Child Mode Tips

- If a child is myopic, use the adult mode to get the best estimate of refraction. The child mode infers accommodation based on a typical three-year-old hyperope.
- If you are using cycloplegia, always use the adult mode to get the best estimate of refraction.

Replacement and Recycling of Battery

Replacing the Battery

1) Open the battery cover located on the underside of the unit by sliding it in the direction indicated by the arrow and lifting out.
2) Rotate the lever holding the battery in clockwise direction until the battery is unobstructed.
3) Carefully tip the unit to allow the battery to slide out of the compartment.
4) Insert the new battery into the compartment in the direction of the arrow on the battery itself, so that the terminal end enters the compartment first.

NOTE: Insert the battery only as directed. Failure to do so will prevent the instrument from functioning.

5) While pushing in on the battery, rotate the lever in a counter-clockwise direction until it covers the battery.
6) Replace the cover by lightly pushing in on the raised end until it is level and sliding the cover in the opposite direction of the arrow until it locks into place.

Charging

- A charged unit can test patients for approximately 3 continuous hours.
- With ~ 10 -15 minutes of on time remaining, the low-battery indicator will begin to flash on the display. When low-battery indicator is steady, battery must be recharged.
- To charge, place the unit completely and firmly into the stand. Unit automatically controls charge into battery when used with Welch Allyn approved 710 series chargers (Instrument will fit into the stand only one way).
- Unit will turn off when charging.
- To prolong on-time, press three buttons simultaneously to shut down.

Recycling Lithium Ion Battery

Welch Allyn now employs the services of an agency which can disassemble and recycle all components of rechargeable batteries so that nothing gets landfilled or incinerated. Should you wish to dispose of your expended Welch Allyn rechargeable battery via recycling (in the U.S. and Canada only), please send to:

Welch Allyn
RECYCLE BATTERY
4341 State Street Road
Skaneateles Falls, NY
13153-0220

Welch Allyn Canada
RECYCLE BATTERY
160 Matheson Blvd. East
Mississauga, Ontario
CANADA L4Z 1V4

For locations outside the U.S. and Canada consult your local recycling authority for correct disposal of batteries.

Screening Mode and Software Updates

Screening Mode

SureSight has an available screening mode to facilitate screening refraction by non-specialists. In this mode:

- No axis is displayed
- Power readings are displayed to 1 decimal place only
- In child mode:
  - Refractive difference **D** the difference in mean spherical power between the two eyes is displayed.
  - *An asterisk on a reading in child mode indicates it is in AAO pre-school referral range.

To place your SureSight in screening mode:

1) Open the battery cover located on the underside of the unit by sliding it in the direction indicated by the arrow and lift up.
2) Rotate the lever holding the battery in and lift the battery from its compartment.
3) View the DIP switches inside the battery compartment located on the button side of the unit.

Using tweezers or another appropriate tool, pull the second switch (starting with the side of the unit with the handstrap) up towards the bottom of the SureSight.

Updating SureSight Software

If it is necessary or desired to update the unit software:

1) Connect the 9-pin female side of the cable supplied with the software disk to a PC (IBM compatible, 486 processor, Windows 3.1 or higher) COM1 or COM2 RS 232 port.
2) Connect the modular jack end of the cable to the RS232 port on the bottom of the SureSight (when SureSight is powered down).
3) Insert floppy disk into PC's 3.5" floppy disk drive.
4) Run a:\setup to begin update.
5) Follow the prompts displayed on the PC.

Hand Strap Replacement

1) Position the unit so that the hand strap is facing up and the battery door compartment is toward you.
2) Push the hand strap forward until the square notches beneath it are visible; hold the strap in this position with one hand.
3) Insert the tool provided into one of the notches and press outward until the fastener is released.
4) Repeat step 3 on the other fastener.
5) Insert the fasteners of the new strap into the appropriate slots, so that "Welch Allyn" can be read.
6) Finally, pull on the strap to ensure that it is seated properly.

Cleaning and Sterilization of the SureSight

NOTE: Excess solution entering the assembly could damage internal components. Use caution to ensure cloth is not saturated with solution. Cleaning solutions should be sprayed on the soft cloth rather than directly on the SureSight device.

Do not sterilize SureSight or any of its components.

All windows on the SureSight can be cleaned with a soft cloth moistened with 70% Isopropyl Alcohol or any standard window cleaner.

Keep front window clean to insure proper function.

The remaining housings, softgrip, handstrap and stand may be cleaned with either a dry, soft cloth or a soft cloth moistened with any of the following: 10% Clorox solution, soapy water, 70% Isopropyl Alcohol, alcohol pads, standard window cleaner.

Service, Calibration, and Warranty Information

The serial number is located on a label inside the battery door.

Warranty

SureSight Instrument

Welch Allyn, Inc. warrants the SureSight instrument to be free of original defects in material and workmanship and to perform in accordance with manufacturer's specifications for a period of one year from the date of purchase. If this instrument or any other component thereof is found to be defective or at variance from the manufacturer's specifications during the warranty period, Welch Allyn will repair, replace, or recalibrate the instrument or component(s) at no cost to the purchaser.

This warranty only applies to instruments purchased new from Welch Allyn or its authorized distributors or representatives. The purchaser must return the instrument directly to Welch Allyn or an authorized SureSight distributor or representative and bear the cost of shipping.

This warranty does not cover breakage or failure due to tampering, misuse, neglect, accidents, modification or shipping, and is void if the instrument is not used in accordance with manufacturer's recommendations or if repaired or serviced by other than Welch Allyn or a Welch Allyn authorized representative.

NOTE: Return of the instrument registration card is required for proof of purchase and warranty validation, and to automatically receive free software upgrades that may occur during the warranty period.

Service and Warranty

For customers in North America, please return instruments requiring service to Welch Allyn Technical Service Department listed below or to an authorized Welch Allyn Technical Service Department.

Technical Service Department
Welch Allyn, Inc.
4341 State Street Road
Skaneateles Falls, NY 13153-0220
Telephone: 1-800-535-6663
Fax: 1-315-685-4653 (Technical Services)

In Canada:

Telephone: 1-800-561-8797
Fax: 1-905-890-0008

SureSight Rechargeable Battery

Welch Allyn Lithium Ion batteries are warranted by Welch Allyn for two years from date of manufacture (when used in Welch Allyn instruments only). Defective batteries will be replaced on a pro rata basis should failure occur prior to expiration date on battery.

Calibration and Maintenance

When the calibration symbol is shown, it indicates that it has been 12 months since the unit was last calibrated. It is recommended that you send the unit in for re-calibration.

Welch Allyn recommends that the SureSight be recalibrated annually. Arrangements may be made by returning the SureSight registration card or by contacting Welch Allyn's Technical Service Department. A moderate fee is charged for re-calibration.

Welch Allyn®
SureSight™

4341 State Street Road
Skaneateles Falls, NY 13153-0220